PATENT
Attorney Docket No.: 34655-703.831

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Inventor: Alan Breen Application No.: 10/520,489 Filed: January 7, 2005 Title: METHOD FOR IMAGING THE RELATIVE MOTION OF SKELETAL SEGMENTS	Confirmation No.: 6542 Examiner: Helene C. Bor Group Art Unit: 3768 Customer No.: 21971

FILED ELECTRONICALLY ON: 10/10/08

DECLARATION OF ALAN BREEN UNDER 37 C.F.R. § 1.131

I, **Alan Breen**, declare as follows:

1. I am the inventor of all of the claims of the patent application identified above originally filed as **PCT/GB2003/002934** on July 8, 2003, claiming priority to **GB 0215848.3** filed July 9, 2002, and to **GB 0226264.0** filed November 11, 2002, and inventor of the subject matter described and claimed therein.

2. Prior to December 13, 2001, I conceived of the idea of an apparatus for the measurement of skeletal joint motion in a subject comprising a passive motion device having a horizontal passive motion platform composed of a horizontal laterally movable platform in which movement of the laterally movable platform is continuously driven during sampling of images as described and claimed in the subject patent application in this country, a NAFTA country, or a WTO country, as evidenced by the following:

a. In a letter dated prior to December 13, 2001 (**Exhibit A**), drawings for the passive motion platform are discussed which I had previously requested drafted.

3. I was continuously diligent in reducing the idea identified above to practice, as evidenced by the following:

a. Subsequent to writing the letter noted in 2.a. *supra*, and prior to December 13, 2001, I had the drawings refined, and had the apparatus made. The apparatus was then used in a validation study of a method of quantifying the relative motion between vertebrae using x-ray motion sequence. Such method and such validation was performed in conjunction with a study entitled "Kinematics of passive lumbar spine motion" for which I submitted an ethics application to the Salisbury Local Ethics Committee, Salisbury, UK, dated prior to December 13, 2001, and which was entitled: "Kinematics of passive lumbar spine motion" (the "Ethics Application"), attached as **Exhibit B**.

b. The Ethics Application references the apparatus to be used in the study, describing the apparatus as "a passive motion apparatus which attaches to an x-ray table to study [relative motion between vertebrae] without the use of skeletal muscles."

c. In the Ethics Application it is proposed to use x-ray motion sequences from the passive motion apparatus which attaches to an x-ray table to determine "whether treatment has mechanical effects on spine linkages" without the influence of the spinal muscles. The goal of the study was to study was to "establish normative values for lumbar intersegmental passive motion characteristics [and] compare these motion characteristics before and after a standardised lumbar spine manipulation." In the outline of the project, it is disclosed that "the videotaped sequences will be digitised and the motion analyzed for relative mobility of lumbar segments of pre and post-manipulation sequences."

d. Michael Kondracki is listed on the Ethics Application as a co-investigator. However, notwithstanding his status as a co-investigator on the Ethics Application, I believe that I am the sole inventor of the claims contained in this patent application.

e. Subsequent to approval of the Ethics Application, the study was run using the apparatus, data were analyzed, and results determined. Results of the study conducted pursuant to the Ethics Application, were presented in the European Journal of Chiropractic, 2002, 50, 27-32, titled: "Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings" by A. Breen, J. Muggleton, M. Kondracki, J. Wright & A. Morris **(Exhibit C)**, which was published less than one year before I filed GB 0215848.3 filed July 9, 2002, to which the present application, 10/520,489 claims priority.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001.

Executed on this 2nd day of October 2008.

Alan Breen, D.C., Ph.D.

AECC

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC

An Associate College of the University of Portsmouth

Exhibit A — REDACTED

D.H. Antrobus, D.C. and Mr. R. Clewley,
Atlas Clinical Limited,
Unit 51,
Britannia Way,
Litchfield,
STAFFORDSHIRE.
WS14 9UY

Dear David and Rob,

Many thanks for the drawing of the tabletop device for DVF. Mike Kondracki and I have discussed it and the basic idea seems very good. It is difficult to know how best to go over this with you so I am sending you a copy of the drawing with some pencilled questions written on it. We will ring you in the next few days.

I would just like to reiterate our commitment to this venture which is fundamental to the DVF research programme in its present phase. We are very grateful for your help.

Best wishes for the New Year.

Yours sincerely,

A.C. Breen, D.C., Ph.D.,
RESEARCH DIRECTOR

Encl.

cc. M. Kondracki.

Exhibit B — Redacted

SECTION 1	Details of applicant(s)

1. Short title of project *(in not more than 6 words)*
   Kinematics of passive lumbar spine motion

   Full title

   Normal kinematic parameters for passive motion of the lumbar spine intervertebral linkages and the effects of spinal manipulation.

   Summary of practical benefits/improvements in patient care which are envisaged

   1) Will provide a basis for the diagnosis of lumbar spine instability.
   2) Will provide insight into the effects of spinal manipulation.

   Both of these results will inform clinical decision-making in the case of patients with low back pain.

2. Applicant *(All correspondence will be sent to this address unless indicated otherwise.)*

   Surname: KONDRACKI (BREEN   Forename: MICHAEL ALAN)   Title:

   Present appointment of applicant:

   Research Fellow - Anglo-European College of Chiropractic
   (Research Director - Anglo-European College of Chiropractic)

   Qualifications:

   D.C., M.Sc.
   (D.C., Ph.D.)

   Address:

   Anglo-European College of Chiropractic, 13-15 Parkwood Road, Bournemouth, Dorset BH5 2DF.

   Tel: 01202-436276   Fax: 01202-436278

3. Other workers and departments/institutions involved

   - A.C. Breen and M. Kondracki
   - Dr. A. Morris, Consultant Radiologist, X-ray Department, Salisbury District General Hospital.
   - Mrs. J. Sword, Superintendent Radiographer, X-ray Department, Salisbury District General Hospital.

4. Signature of relevant bodies

   I undertake to carry out the work in accordance with the principles of the Declaration of Helsinki (copy available from the LREC secretary) and its amendments.

   Signature of applicant ....Kondracki....................

   Signature of Head of Department/Supervisor/Principal in General Practice with overall responsibility for the project .... D

   I am fully aware of the details of this project and happy for it to continue as outlined here.

   Signature of Clinical Director

SECTION 2	Details of project

This section must be completed. A copy of the protocol should be enclosed with the application form, but it is not sufficient to complete questions by referring to the protocol.

5. Aims and objectives of project

- To establish normative values for lumbar intersegmental passive motion characteristics in male subjects in the age range 20 to 65.

- To compare these motion characteristics before and after a standardised lumbar spine manipulation.

6. Scientific background of study

- We have developed and validated a method of quantifying the relative motion between vertebrae using x-ray motion sequence in previous collaborations and with the Department of Mechanical Engineering at Southampton University (see reference list). Recent clinical developments have led to the establishment of a new measure of the stability of spinal linkages related to laxity (16). This is one of the main thrusts of our current work and requires investigation in both normals and patient groups before we can be sure of its clinical value.

- The value of spinal manipulation has now received acknowledgement (17). However, it is not known whether the treatment actually has mechanical effects on spine linkages. For this it will be necessary to study intervertebral motion before and after manipulation.

- We have developed a passive motion apparatus which attaches to an x-ray table to study this without the influence of the spinal muscles.

7. Brief outline of project

Thirty male subjects will undergo lumbar spine passive flexion/extension and sidebending, using a custom-designed passive motion table, during a 15-second fluoroscopic examination of the lumbar spine (dose-area products will be determined for all examinations). An experienced chiropractor will then examine the subjects to determine whether the lumbar segments are freely mobile, relatively stiff or fixed. In one-half of the sample, the fixed or stiff segments will be manipulated gently by the same chiropractor. Immediately after manipulation the subjects will undergo a repeat 15-second fluoroscopic screening of the lumbar spine. Following this, the videotaped sequences will be digitised and the motion analysed for relative mobility of lumbar segments of pre and post-manipulation sequences. The kinematic analysis will use the same classification as that used by the clinician, i.e. freely mobile, stiff or fixed. When all results have been determined for all subjects the clinical data will be compared with the kinematic data and assessed for agreement in both vertebral level location and degree of mobility. The post-manipulation data can then be used to determine if any significant change has occurred. It is anticipated that the radiographic element of the study will require one day for each group of 10 subjects. The entire project will therefore necessitate no more than three days utilisation of the hospital fluoroscope. Images from this study will also be used to investigate and establish normative values for lumbar spine stability/laxity, using our newly-developed laxity index, for asymptomatic individuals.

Original article

Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings

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Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings
A. C. Breen, J. Muggleton, M. Kondracki, J. Wright & A. Morris. *European Journal of Chiropractic*, 2002, **50**, 27–32
The present paper describes a comparison between lumbar spine motion palpation findings and the objective assessment of passive intervertebral side-bending using X-ray fluoroscopic sequences. Sixteen male volunteers underwent conventional lumbar motion palpation by an experienced chiropractor prior to fluoroscopic screening in passive side-bending motion. The X-ray sequences were analysed for intervertebral rotational motion using an image processing technique and the results were compared with the palpation findings. Twenty-five lumbar motion segments between L2 and L5 met the reliability criteria for assessment. Palpation suggested that 10 of these were 'free' and 15 'partially fixed'. (No complete fixations were found.) The 'partially fixed' segments were found to have 2.3° less range than the 'free' segments ($P=0.08$). These results are encouraging and provide support for the scientific validity of palpation as a clinical technique for locating vertebral levels and detecting intervertebral range restrictions.

Introduction

The palpation of osseous landmarks is one of the most common examination procedures in European chiropractic (Pedersen 1994). However, its role in clinical decision-making may be out of proportion to its reliability. The 1980s and early 1990s saw a number of serious attempts to evaluate this gap with studies involving calibration against known standards, test–retest reliability, internal consistency, and inter- and intra-observer reliability (Breen 1992). The statistical methodologies needed to underpin these evaluations were also reviewed (Haas 1991), helping to promote an appreciation of the limits of reliability and what reasonable limits could be.

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Palpation of the spine has received most of the attention directed at reliability (Russell 1983), addressing *in vivo* observer variations in the cervical (Mior *et al.* 1985), thoracic (Christensen *et al.* 2001) and lumbar spines

Exhibit C

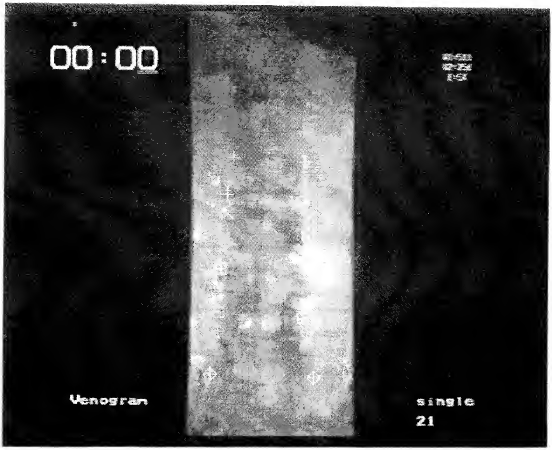

Figure 1. Image from a digital fluoroscopic motion sequence of the lumbar spine. The cursor marks record the coordinates of the instantaneous vertebral position.

(Keating *et al.* 1990; Maher & Adams 1994). Validity against a known standard has proved to be even more difficult, the construction of model environments providing the certainty of a 'gold standard' at the expense of realism (Harvey & Byfield 1991). These investigations seldom distinguished between the amount of intersegmental movement during active or passive spinal motion, the stiffness of the motion segments to pressure (joint challenge), or the patient's reaction to either. In summary, the studies so far have suggested that motion palpation is not a very reliable procedure, especially between observers, and there is little evidence that it detects actual stiffness in spinal motion segments. The evaluation of this requires a comparison between palpation findings and objective segmental motion measurements in living subjects.

However, such a technique has existed since the late 1980s, when the present authors' research group embarked on the development of a device based on the image processing of fluoroscopic spinal motion sequences (Fig. 1). They have developed computational algorithms for the analysis and display of the kinematics between vertebrae, and the system has gone through various stages of refinement aimed at reducing the laboriousness of the process (Breen *et al.* 1989, 1990, 1993). One of the most helpful steps in this has been the automatic tracking of images (Muggleton & Allen 1997), which allows the operator respite from coordinate marking, and along with modern computer storage capacities and processor speeds, now enables many more images in the sequence to be accessed.

The present paper describes a comparison between lumbar spine motion palpation findings and the objective assessment of passive intervertebral side-bending using digitized X-ray fluoroscopic sequences. This was part of a larger study done to inform the development of the system. At the time of the present study, the authors' tracking method was limited to coronal plane (side-bending) motion.

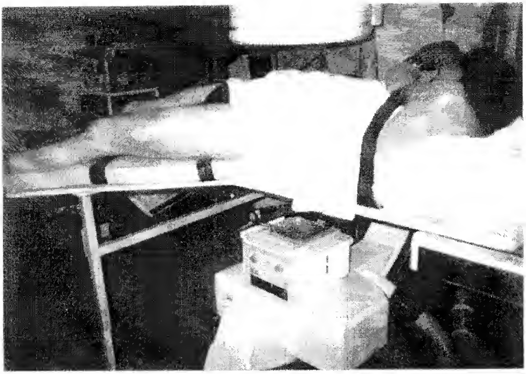

Figure 2. Subject undergoing passive side-bending motion during screening.

Subjects and methods

Subjects

Sixteen male volunteers were included in the present study. None had suffered back pain in the previous year or had manipulation to their lumbar spines in the previous month. Informed consent was obtained and the study carried ethical approval from the Salisbury Local Research Ethics Committee, Salisbury, UK.

Palpation method

Prior to examination, the age, height and weight of the subjects were recorded. Each subject then sat on a flat bench with their feet in contact with the floor and their hands on their thighs. The palpator was an experienced chiropractor who first located the spinous processes from L1 to S1 and marked them with a skin pencil (Burton *et al.* 1990). The palpator's thumb was placed against the lateral aspect of each interspinous junction so that both spinouses could be felt. The subjects were encouraged to relax and allow passive side-bending motion of the trunk. This was initiated and controlled by the palpator's other hand, which side-bent the trunk, first left, then right, with a contact across the middle trapezius region. To avoid altering flexibility by virtue of the palpation method itself, no pressure ('joint challenge') was exerted against the spinouses. Each motion segment was recorded as being either free, partially fixed or completely fixed.

Acquisition of images

After palpation, subjects were sedentary until, within 20 min, they underwent passive side-bending in the supine position whilst undergoing fluoroscopic screening of their lumbar spines (Fig. 2). This was carried out in the Special Procedures Room of the X-ray Department at Salisbury District Hospital, Salisbury, UK. A motorized table was fixed to a digital X-ray machine (Polystar, Siemens, Munich, Germany). This equipment incorporates an above-table image intensifier and an automatic exposure control. The table's base section could be abducted by 80° (40° left to 40° right). Screening was executed with gonadal shielding after a brief trial of the range of motion without exposure to ensure that the subject was comfortable at the extremes of the range, familiar with the procedure and adequately stabilized. Additional lead rubber shielding was used to reduce the flare produced during screening. The central X-ray beam was centred at the level of L3 and the sequence of motion was from neutral to 40° left to 40° right, then back to neutral. Exposure times, current (mA), voltage (kV) and absorbed radiation were recorded.

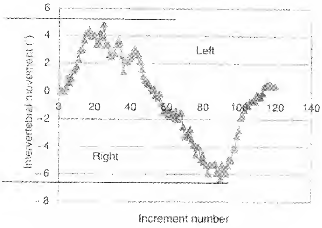

Figure 3. Range of motion measurement. (▲) L4–5.

During screening, a personal computer interfaced with the analogue output of the image intensifier sampled the image sequence. This was coordinated with the motorized table motion and the exposure. Images were digitally sampled at a rate of five frames per second with the simultaneous recording of time code on each frame. Files were stored on compact disc for later analysis.

Processing of image data

All images were subjected to an automated tracking protocol based on the electronic template labelling of each vertebral body (Muggleton & Allen 1997). This procedure generated a vertebral angle for each segment in each frame, and subsequently, the angles between them by subtraction. Intervertebral angles were generated for approximately 120 frames of the motion, which constituted the entire range. The range of intersegmental side-bending was measured for each vertebral motion segment as the greatest angular difference between end-of-range positions (Fig. 3). This procedure was undertaken by a different observer to the palpator.

Reliability of image analysis

Reliability was addressed in two ways. The first was by selecting three subjects thought to represent the spread of tissue types across the sample and tracking their motion sequences 10 times for each of the 120 increments of rotational motion at each lumbar segment. As a result of this, the L1–2 level was rejected as producing unacceptable errors because of out-of-plane images, as was the L5–S1 because of the small motion range at that level. Two standard deviations of the mean differences between tracking sequences were considered to represent the instrument measurement errors (IMEs; Haas 1991) for each motion segment.

The second reliability assessment consisted of analysing each subject twice. The second trace of motion for each vertebra had to overlie the first on visual inspection, especially at the extremes of range. Those that did not were rejected from the analysis. The differences between ranges for all motion segments at each individual level were analysed for significance using the SPSS PC+ Version 10 computer program.

Table 1. Characteristics of subjects and X-ray dosage ($n = 14$)

Variable	Mean (± SD)	Range Minimum	Range Maximum
Characteristic			
Age (years)	29.9 ± 6.5	19	40
Body mass index*	24.1 ± 2.0	20.9	28.7
X-ray dosage			
Voltage (kV)	73.3 ± 3.7	68	83
Current (mA)	1.2 ± 0.2	0.9	1.8
Time (min)	0.49 ± 0.05	0.4	0.6
Absorbed dose (mSv)	0.17 ± 0.08	0.1	0.3

*Calculated as the subject's weight (kg) divided by the square of her or his height (m).

Results

The present study population were relatively young and fit, with a mean age (± SD) of 29.9 ± 6.5 years and a mean body mass index (± SD) of 24.1 ± 2.0 (Garrow 1988) (Table 1). All participants tolerated the examination easily. The mean X-ray dose was equal to approximately two-fifths of the dose of a plain posterior–anterior lumbar film (Wall & Hart 1997). This was mainly attributable to short exposures and low milliamperage.

The instrument measurement errors for the L2–3, L3–4 and L4–5 motion segments were 4.0°, 2.3° and 1.7°, respectively. Twenty-five palpated motion segments from L2–3 to L4–5 in 14 of the subjects met the reliability criteria for analysis. Ten of these had been recorded as 'free' and 15 as 'partially fixed'. None were recorded as completely fixed, possibly reflecting the age and asymptomatic nature of the population.

The mean ranges (± SD) of the 'free' and 'partially fixed' segments from image analysis were 15.1 ± 3.71° and 12.8 ± 3.19°, respectively. This average difference of

Table 2. Palpation against objective intervertebral rotation measurements

Free segments		Partially fixed segments	
Subject	Range (°)	Subject	Range (°)
L2–3			
DE	15.25	RJ	12.5
		RG	11.00
Mean (± SD)	15.25	11.75 ± 1.06	
L3–4			
DE	16.5	RG	11.5
RJ	9.75	OT	14
DK	18.5	GD	16.5
BM	18.25	GP	15
IM	11.25		
Mean (± SD)	14.85 ± 4.07	14.25 ± 2.10	
L4–5			
DE	17	MG	10.5
RJ	10	RG	15
JW	14.25	MM	17.75
BM	20.25	OT	14
		WO	10.5
		DK	4.24
		GD	14
		JM	12
		IO	13.5
Mean (± SD)	15.38	12.38 ± 3.80	

2.5° did not quite reach statistical significance ($P=0.08$, two-tailed analysis, unpaired *t*-test assuming unequal variances).

Table 2 shows the subject-by-subject comparison between palpation findings and measured ranges in the subjects. No conclusion can be made about the differences between the 'partially fixed' and 'free' segments at the L2–3 level since the mean difference between them of 3.5° was inside the IME of 4.0° for this level. At L3–4, these differences were small and also within the IME. At L4–5, the mean difference of 3° was greater than the IME of 1.7°, although not statistically significant ($P=0.28$, Mann Whitney *U*-test).

Discussion

Reliability of the objective measure

The use of automated image tracking and the possibility of averaging repeated analyses provides a method for minimizing errors, overcoming an important impediment in this work. However, acceptable reliability has been possible using such a system without automated tracking (Humphreys *et al.* 1990). The above authors calculated interobserver IMEs of 2° (four observers) and intra-observer IMEs of 0.65° based on images where the central ray was aligned at the level of interest (L4–5), optimizing reliability. However, there are limits to this. Coyle (1987) demonstrated that, on a conventional X-ray image of a vertebra, it would be difficult to reliably calculate an intervertebral angle under 2° with an attributable coordinate mark. However, image resolution is constantly improving with fluoroscopy, which will reduce this problem.

The statistical power of studies to detect differences is lowered when the effect (in this case, degree of intervertebral stiffness) is low. Therefore, studies using young, asymptomatic subjects are not ideal, since their motion segments can be expected to be relatively flexible. In this regard, the present data can be regarded as a starting point for future work with symptomatic populations. In such studies, skin-marking over the spinouses is recommended.

Active or passive motion?

The development of a non-weight-bearing passive motion apparatus was compatible with the investigation of disco-ligamentous and involuntary muscular effects on intersegmental motion. By contrast, active motion in a weight-bearing position would apply the additional effects of disc and facet compression, and voluntary muscle activity. It would have been more representative of passive motion if the palpation in the present study had been undertaken with the patient on the passive motion table, but less representative of motion palpation techniques.

Conclusion

The present study shows that motion palpation findings may reflect actual *in vivo* intervertebral motion. However, the use of a small number of young, asymptomatic subjects undoubtedly weakened its statistical power. Nevertheless, these results are encouraging, and future work with a larger number of symptomatic subjects involving sagittal plane motion would yield a larger number of segments and a greater selection of kinematic patterns for analysis. This would confirm (or otherwise) the findings reported by the present authors.

Acknowledgements

We gratefully acknowledge the financial support of the European Chiropractors' Union Research Fund for the programme of work of which this was a part. We also thank all the volunteer subjects who gave freely of their time to help us.

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